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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,345

12/20/2005

Udo Krupka

05552.1463

5930

22852

7590

06/08/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

06/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,345	Applicant(s) KRUPKA, UDO	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) 36-39 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-28, 30, 33-35, 40, 42 is/are rejected.
- 7) ☐ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 24-30 and 33-42 are pending in the application.
2. In the prior action, mailed on October 8, 2008, claims 24-42 were pending; with claims 36-39 and 41 withdrawn from consideration; and claims 24-35, 40, and 42 under consideration and rejected.
3. In the Response of April 8, 2009, the Applicant amended claims 24, 26, and 28; and cancelled claims 31 and 32.
4. Claims 24-30, 33-35, 40, and 42 are under consideration.
5. Because the action raises a new ground of rejection with respect to claims 27 and 28, the action is made Non-Final.

Claim Objections

6. **(New Objection- Necessitated by Amendment)** Claim 28 is objected to because of the following informalities: reference to the “at least one of the amino acid found at positions...,” should read - - at least one of the amino acids found at positions....- - . Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. **(Prior Rejection- Withdrawn)** Claims 24-33 and 40 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In view of the amendment of the claims to read on isolated or purified polypeptides, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(Prior Rejection- Maintained)** Claims 28, 30-35, 40, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn from cancelled claims 31 and 32.

As previously, claim 28 is treated as representative. This claim reads on a peptide comprising “at least 5 consecutive amino acids from SEQ ID NO: 12, and comprising “at least one of the amino acids found at” the indicated positions of that sequence. The claims were rejected on two grounds.

First, it was not clear if the claim is requiring that the consecutive amino acid sequence from SEQ ID NO: 12 includes the indicated amino acid position, or of the claim is requiring a consecutive sequence from claim 12, and an amino acid position corresponding to that identified amino acid positions

Second, it was not clear what is meant by the language requiring that the polypeptide comprises one of the indicated amino acid positions. For example, it is not clear if the claim is requiring that the polypeptide includes a position 73, includes a position 73 having the same amino acid that is found in position 73 of SEQ ID NO: 12, or if the polypeptide need only include the amino acid found in the position 73 of SEQ ID NO: 12.

The amendments to the claims are not found sufficient to overcome the rejection. At present, the claims appear to read on any polypeptide containing at least 6 consecutive amino

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acids of SEQ ID NO: 12, wherein the amino acids comprise one of the amino acids found in indicated positions of the sequence. I.e., the claim appears to read on any fragment of the sequence so long as the sequence includes one of a Ser, Gln, Leu, Val, or Arg (the amino acids found in the indicated positions). However, reference to the arguments in traversal and the specification indicates that the Applicant intends to claim a peptide - - of at least 6 consecutive amino acids of SEQ ID NO: 12, wherein the consecutive amino acids include a sequence comprising at least one of - - the indicated positions.

In addition, claims 33-35, 40, and 42 are also rejected on a new basis necessitated by the amendments to the claims. Claim 31 has been cancelled from the application. However, the indicated claims still depend, either directly or indirectly, from this claim. The claims are therefore also on the grounds that the claims depend on a cancelled claim, because by doing so it is not clear what the claims are further limiting.

Clarification of the scope of the claims is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Extended and Maintained)** Claims 25, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Applicant traverses the rejection on the basis that the specification provides an example of a peptide that would react to such antibodies (a fragment of the SEQ ID NO: 13), and that those in

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the art would be capable of contemplating mutants of such sequences. The argument is not found persuasive. This rejection is also extended to claim 27 for the same reasons as indicated with respect to claims 25, 40, and 42 in the prior action.

As was indicated in the prior action, there is significant uncertainty in the identity of what peptides sharing at least 94% identity to SEQ ID NO: 13 would retain that ability to react with sera from the indicated population of donors. The Applicant makes no argument and presents no evidence in traversal of these concerns.

Further, while written description support may not require word-for-word support in the application, the mere functional identification of the desired genus of compounds is not considered, in the present application, to provide adequate descriptive support for the claimed genus. While the Applicant may have had a idea that the genus exists, there is inadequate descriptive support to demonstrate that the Applicant was in possession of the identity of the members of the genus as is required to meet the written description requirement.

Furthermore, the present application does not permit those in the art to visualize or recognize the claimed genus as asserted on pages 10-11 of the Response. While those in the art may be capable of visualizing sequences with at least 94% identity to SEQ ID NO: 13, the rejected claims impart an additional functional requirement, for which no correlating non-functional characteristic has been provided. In view of this, and as no examples of any mutants of SEQ ID NO: 13 (or its fragments) that meet the functional requirement have been provided, the application fails to make either of the two types of showings demonstrating adequate descriptive support indicated in the prior action.

For the reasons above, and the reasons of record, the rejection is maintained.

12. **(Prior Rejection- Maintained)** Claims 24, 26, 33-35, 40, and 42 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID NO: 13, does not reasonably provide enablement for the use of any polypeptide comprising an amino acid sequence of at least 94% identity to that sequence. The Applicant traverses the rejection on the basis that those in the art would be able to determine what variants retain the activity of SEQ ID NO: 13; because, while biotechnology may be an unpredictable art, such does not preclude a finding of enablement; and because those in the art would be able to identify all nucleic acids encoding a polypeptide sharing at least 94% identity to SEQ ID NO: 13 and screen them for the sharing activity with SEQ ID NO: 13.

Applicant's arguments are noted but are not found persuasive. Applicant's arguments may be found persuasive if the rejection was based on a finding of lack of enablement based on a consideration of only one or two of the factors identified in the prior action. However, in the present case, the claims are broadly drawn to cover a large number of mutant sequences, the structures and functions of which are not known, and cannot easily be predicted, and where the application itself provides little information with respect to the functions or structure of the protein of SEQ ID NO: 13, and no identification or characterization of any mutants thereof. Thus, while those in the art may be capable of performing screening assays, and as certain forms of screening may be routine, the teachings in the application nonetheless fail to provide enabling support for the full scope of the claimed invention. The rejection is therefore maintained.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **(Prior Rejection- Withdrawn)** Claims 28 and 31 were rejected under 35 U.S.C. 102(b) as being anticipated by Quinnan et al. (WO 00/07631). In view of the amendment of the claims require that the peptide comprises at least 6 consecutive amino acids of SEQ ID NO: 12, the rejection is withdrawn.

15. **(Prior Rejection- Maintained)** Claims 28, 33-35, and 40 were rejected under 35 U.S.C. 102(b) as being anticipated by Langley et al. (EP 0533492). Applicant's arguments are not found persuasive. As was indicated above, the Examiner is not persuaded by Applicant's arguments regarding the clarity of the claims. In particular, as was described above, the broadest reasonable interpretation of the claims appears to read on any polypeptide containing at least 6 consecutive amino acids of SEQ ID NO: 12, wherein the amino acids comprise one of the amino acids Ser, Gln, Leu, Val, or Arg. Such is met by the peptides disclosed by the reference.

The sequence of Figure 1 of the reference discloses such a sequence. See e.g., the sequence of the sixth line of amino acids (beginning Gly Tyr Arg Trp Met Cys), which comprises an Arginine, the amino acid found in position 73 of SEQ ID NO: 12, and which sequence is also found in amino acids 29-34 of SEQ ID NO: 12. Thus, the reference teaches a polypeptide comprising a sequence of at least six consecutive amino acids of SEQ ID NO: 12,

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wherein the sequence comprises the amino acid found at position 73 of SEQ ID NO: 12 (i.e. an arginine). The arguments are not found persuasive, and the rejection is therefore maintained.

16. **(New Rejection)** Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by GenPept BAC17521. The claim has been described above. The reference teaches a polypeptide comprising a sequence of at least 6 amino acids of SEQ ID NO: 12, including a sequence corresponding to residues 71-77 of SEQ ID NO: 12 with an arginine at the position corresponding to amino acid 73 of SEQ ID NO: 12. See e.g., residues 562-568 of the GenPept sequence. The reference therefore anticipates the claim.

Claim Rejections - 35 USC § 103

17. **(Prior Rejection- Withdrawn)** Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinnan et al. (WO 00/07631- supra). Applicant's arguments with respect to this rejection are found persuasive. The rejection is therefore withdrawn.

Conclusion

18. No claims are allowed. Claim 29 is objected to for depending from a rejected claim.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648